Received: 29 September 2020 | Revised: 23 December 2020 | Accepted: 23 December 2020

DOI: 10.1111/epi.16818

Epilepsia®

SPECIAL REPORT

Automated seizure detection using wearable devices: A clinical practice guideline of the International League Against Epilepsy and the International Federation of Clinical Neurophysiology

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Abstract

The objective of this clinical practice guideline (CPG) is to provide recommendations for healthcare personnel working with patients with epilepsy on the use of wearable devices for automated seizure detection in patients with epilepsy, in outpatient, ambulatory settings. The Working Group of the International League Against Epilepsy (ILAE) and the International Federation of Clinical Neurophysiology (IFCN) developed the CPG according to the methodology proposed by the ILAE Epilepsy Guidelines Working Group. We reviewed the published evidence using The Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement and evaluated the evidence and formulated the recommendations following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. We found high level of evidence for the accuracy of automated detection of generalized tonic-clonic seizures (GTCS) and focal-to-bilateral tonic-clonic seizures (FBTCS) and recommend the use of wearable automated seizure detection devices for selected patients when accurate detection of GTCS and FBTCS is recommended as a clinical adjunct. We also found a moderate level of evidence for seizure types without GTCS or FBTCS. However, it was uncertain whether the detected alarms resulted in meaningful clinical outcomes for the patients. We recommend using clinically validated devices for automated detection of GTCS and FBTCS, especially in unsupervised patients, where alarms can result in rapid intervention (weak/conditional recommendation). At present, we do not recommend clinical use of the currently available devices for other seizure types (weak/conditional recommendation). Further research and development are needed to improve the performance of automated seizure detection and to document their accuracy and clinical utility.

KEYWORDS

algorithms, automated detection, epilepsy, seizure detection, wearable devices

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This article is published simultaneously in the journals Epilepsia and Clinical Neurophysiology.

1 | INTRODUCTION

The International League Against Epilepsy (ILAE) and The International Federation of Clinical Neurophysiology (IFCN) have joined forces to develop clinical practice guidelines (CPGs) for application of neurophysiological methods in epilepsy. The objective of this CPG is to provide recommendations on the use of wearable devices for automated seizure detection in outpatients with epilepsy in an ambulatory setting, to reduce the morbidity and mortality associated with seizures, and to improve the objective documentation of seizure frequency.

We developed the CPG according to the methodology proposed by the ILAE Epilepsy Guidelines Working Group.[1] The development was evidence-based and consensus-driven. It followed the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.[2,3] The target audience of this CPG is healthcare personnel who are working with patients with epilepsy. The CPG was endorsed by both international societies.

Key point

- This clinical practice guideline addresses automated seizure detection using wearable devices.
- The guideline was developed by a working group of the International League Against Epilepsy (ILAE) and the International Federation of Clinical Neurophysiology (IFCN) using the Grading of Recommendations Assessment, Development and Evaluation (GRADE)system.
- Wearable devices are effective for accurate detection of generalized tonic-clonic seizures and focal-to-bilateral tonic-clonic seizures
- It is uncertain whether the detection alarms result in meaningful clinical outcomes for patients until further research is completed.
- Wearable devices are recommended for detection of tonic-clonic seizures (weak/conditional recommendation).

2 | IDENTIFYING THE TOPIC AND DEVELOPING THE CLINICAL QUESTIONS

There is a need for automated seizure detection using wearable devices, to decrease morbidity and mortality associated with seizures and for objective seizure identification and quantification. Approximately one third of patients with epilepsy are not seizure-free, despite adequate treatment.[4] The unpredictability of seizure occurrence is distressing for patients and their caregivers, and detection provides an element of patient empowerment and an opportunity for intervention. Unpredictability contributes to social isolation and decreased quality of life. Patients with generalized seizures and those with focal impaired awareness seizures are not able to call for help during seizures. Therapeutic decisions in clinical practice, as well as drug trials, use self-reporting of seizures,[5] which is largely unreliable. Studies in video–electroencephalography (EEG) monitoring units have demonstrated that 47%–63% of seizures remain unrecognized by patients,[6] and this is even higher (86%) for nocturnal seizures.[7]

Generalized tonic-clonic seizures (GTCS), including focal-to-bilateral tonic-clonic seizures (FBTCS), may lead to injuries, and constitute the main risk factor for sudden unexpected death in epilepsy (SUDEP), especially in unattended patients, during nighttime hours.[8] Each year, 25% of the patients with GTCS experience at least one serious injury related to the GTCS, causing disability or requiring hospitalization or surgical intervention, and patients with five or more GTCS per year have a 3.5 times higher odds ratio (OR) for injuries, compared with patients who have only one seizure per year.[9] The majority of SUDEP cases that were video-EEG documented occurred after a GTCS.[10] The risk of SUDEP was 27 times higher in patients experiencing GTCS during the preceding year, whereas no excess risk was seen in patients with non-GTCS seizures.[11] The combination of not sharing a bedroom and having at least one GTCS per year was associated with a 67-fold increased risk of SUDEP.[11] The risk of SUDEP increases in association with increasing frequency of GTCS occurrence.[12] Therefore, GTCS (including FBTCS) is the most important seizure type that needs to be detected automatically to decrease morbidity and mortality associated with seizures.

Several large surveys of patients with epilepsy, their caregivers, and healthcare professionals have demonstrated that there was a need for reliable seizure detection using wearable devices (WDs) in the home environment of the patients.[13–17] WDs are becoming widely used, and this trend has reached healthcare applications, including epilepsy: There are hundreds of WDs on the market that measure health parameters and biosignals,[18] and many of them make unsubstantiated claims of detecting epileptic seizures. There is a considerable gap between the rapidly developing field of digital technology and the arguably conservative clinical practice. This is largely due to lack of evidence-based guidelines for clinical implementation of automated seizure detection using wearable devices. The scope of this ILAE-IFCN CPG is to bridge this gap, by reviewing the evidence behind the performance of these devices and recommending their application in patients with epilepsy.

We used the PICO approach (Population, Intervention, Comparator and Outcome) to construct the clinical questions

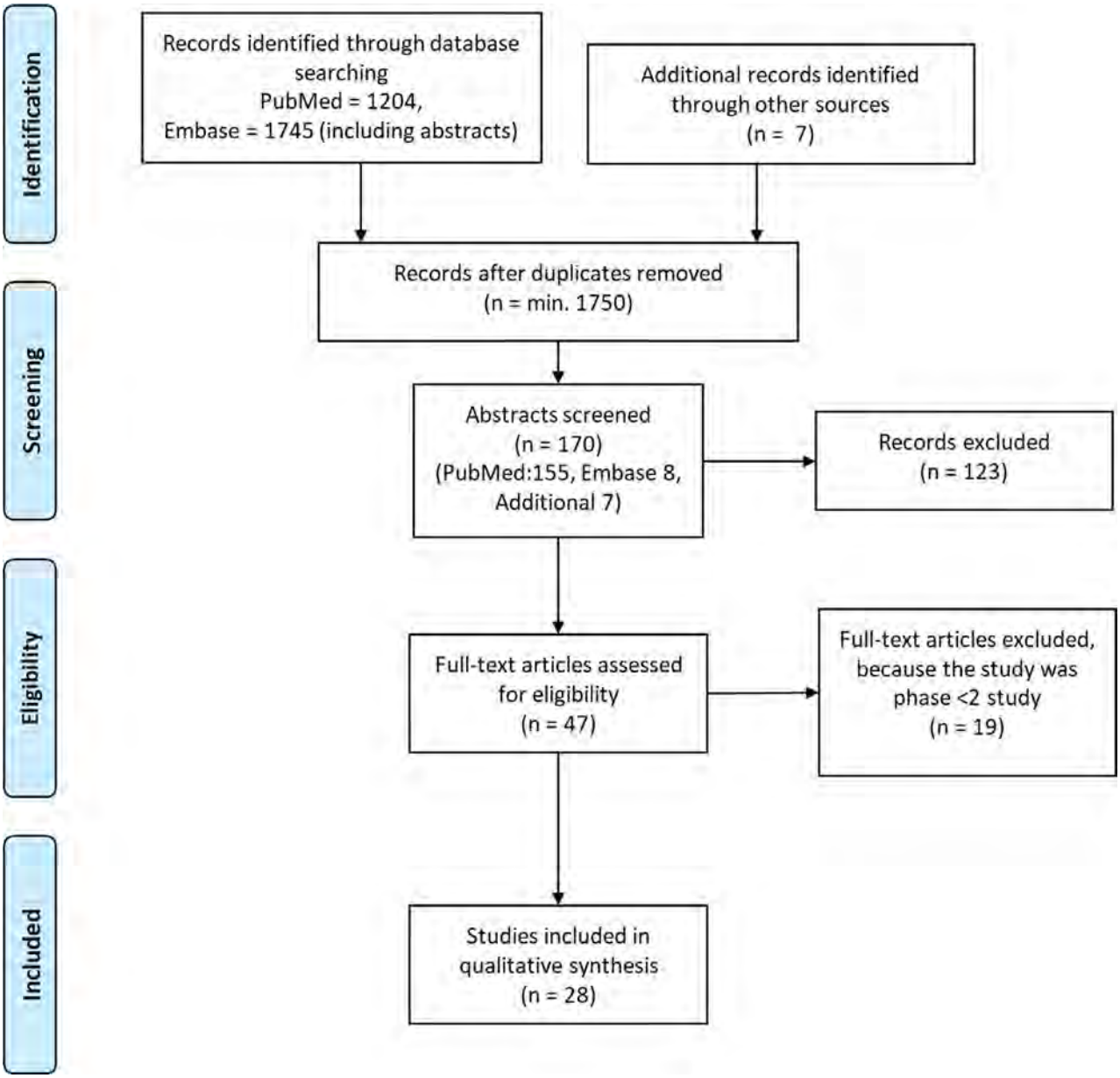

FIGURE 1 PRISMA Flow Diagram,[20] showing the steps of literature search and selection of the published evidence.

Population	Children and adults with epilepsy, who are not seizure-free and who have either (a) GTCS, including FBTCS or (b) focal impaired awareness seizures, without tonic-clonic component.
Intervention	Automated seizure detection using a wearable device and room or bed-placed sensors.
Comparator	Electroclinical seizures identified by trained experts, based on video-EEG or video recordings.
Outcome	Sensitivity, false alarm rate, adverse events, usability.

TABLE 1 PICO (Population, Intervention, Comparator and Outcome)

(Table 1). We aimed at answering the following questions: (1) Can automated devices accurately detect GTCS, including FBTCS? (2). Can automated devices accurately detect impaired awareness seizures without tonic-clonic component?

Evaluation of the efficacy of closed loop systems, where automated seizure detection triggers a therapeutic intervention to stop the seizure, was beyond the scope of this CPG.

3 | ESTABLISHING THE CPG WORKING GROUP

The ILAE Commission on Diagnostic Methods and the Executive Committee of the IFCN each appointed four members of the CPG Working Group, to achieve a multidisciplinary composition and a broad geographic representation.[19] The Working Group and the CPG development protocol were approved by the Guidelines Task Force before starting the literature search.

4 | REVIEWING THE EVIDENCE

We conducted the systematic review of the published evidence, and the results of the systematic review of the published evidence were reported according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement.[20]

We searched in PubMed and EMBASE using the following string: ((automated detection) OR (algorithm AND detection) OR (wearable AND detection)) AND (epilepsy OR seizure). The date last searched was October 16, 2019. In addition, experts were asked to contribute relevant references. We selected studies published as papers in peer-reviewed journals, without language limitations, corresponding to phase 2, 3, or 4 clinical validation trials, according to the previously published standards for testing and clinical validation of seizure-detection devices.[21] Briefly, these phases (Table S1) were based on the key features for validation of seizure-detection devices: subjects, recordings, data analysis and alarms, and reference standard. Depending on how the studies addressed these features, they were classified into phases 0 to 4, where phase 3 studies provide compelling evidence and phase 4 studies are in-field, follow-up studies on the feasibility and utility of the devices in the home environment of the patients.[21] To qualify as phase 3, studies had to fulfill the following criteria: prospective, multicenter study analyzing continuous recordings from a dedicated seizure-detection device, including at least 30 seizures recorded from at least 20 patients (for a sensitivity >90%), with real-time detection of seizures (signal analysis running during the recording) using a pre-defined algorithm with a pre-defined detection cut-off value and reference standard from video or video-EEG recordings interpreted by experts. The phases express the risk of potential bias in the validation studies, which decreases from phase 0 to phase 3. The studies had to specify the key outcome measures: sensitivity and false alarm rate (FAR), reported according to the STARD (Standards for Reporting Diagnostic Accuracy Studies) criteria.[22] For systematic assessment of risk of bias, we have adapted the items from the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) to the specific application for this health technology assessment.[3,23] Bias introduced by patient selection, patient flow, execution of the automated data analysis (seizure detection), and the reference standard were present in phase-2 studies and nonsignificant in phase-3 studies.

The following data were extracted from the studies: (a) signal used for seizure detection; (b) prospective vs retrospective study; (c) real-time vs off-line analysis and seizure detection; (d) seizure type that were analyzed; (e) number of patients with seizures; (f) number of recorded seizures; (g) sensitivity (proportion of true seizures detected); (h) device deficiency time (percentage of time when the device was not functional); (i) latency of seizure detection from seizure onset; (j) false alarm rate, expressed as number of false alarms per 24 hours and as number of false alarms per night (Table 2).

Two independent reviewers screened titles, abstracts, and full-text articles for eligibility criteria. A third reviewer resolved disagreements at the full-text screening phase and the data abstraction phase. The PRISMA flow diagram (Figure 1) shows that of the 1750 relevant citations found, 170 abstracts were screened for eligibility, 47 articles were reviewed in full text, and 28 fulfilled criteria for inclusion in the evidence synthesis. Due to the large heterogeneity in study design and the use of different devices and algorithms, quantitative synthesis (meta-analysis) was not possible. We thus conducted a qualitative synthesis of the included studies (Table 2). Only three studies fulfilled the criteria for phase 3 and two studies for phase 4 (one study reported both phase 3 and 4).[24] The remaining studies were phase 2. We identified several limitations and potential sources of bias, especially for phase 2 studies (Table 2). In particular, offline analysis of the biosignals and the use of several post hoc cut-off values raise the possibility of overfitting to the recorded data set and call to question the generalizability of the results. Important aspects, such as detection latency and device deficiency were often omitted from the reports, and only a few studies were reported according to the STARD guidelines.

Evidence from phase 3 studies for detection of seizures with sensitivity of at least 90% was available only for GTCS, including FBTCS. One study used accelerometer, one study used surface electromyography, and one study used a multimodal device (accelerometry and heart rate) (Table 2). The sensitivity of these devices was between 90% and 96%, with a false alarm rate of 0.2-0.67/24-h. (o–0.03/night). All three devices validated in phase 3 studies have approval for use as medical devices (CE-mark) in the European Union. Two phase 4 studies demonstrated the feasibility of WDs and their usability for detecting GTCS in the home environment of the patients.[24,25] However, it is important to note that most patients included in the phase 4 studies had severe epilepsy and intellectual disability and were living in a residential care setting.

TABLE 2 Review of evidence

Study	Phase	Modality	Study design	Patient age range	Types of seizures
Kramer et al. (2011)[30]	2	Wrist 3D-accelerometer	Prospective/Real-time	Not reported	Motor seizures
Beniczky et al. (2013)[31]	3	Wrist 3D-accelerometer (Epi-care)	Prospective/Real-time	13-63 years (mean 37 years)	Generalized tonic-clonic seizures
Patterson et al (2015)[32]	2	Wristwatch accelerometer (SmartWatch)	Prospective/Real-time	5-41 years	Generalized tonic-clonic, myoclonic/myoclonic-tonic, partial onset with minimal motor component, partial-onset hypermotor, and tonic seizures.
Velez et al. (2016)[33]	2	Wristwatch accelerometer	Prospective/Real-time	19-66 years	Generalized tonic-clonic seizures.
Kusmakar et al. (2017)[34]	2	Wrist accelerometer	Prospective/Offline	Not reported	Generalized tonic-clonic seizures.
Meritam et al. (2018)[25]	4	Wrist 3D-accelerometer (Epi-Care).	Retrospective survey with long-term follow-up. /Real-time	7-72 years (median 27 years)	Generalized tonic-clonic seizures.
Kusmakar et al. (2019)[35]	2	Wrist 3D-accelerometer	Retrospective/Offline	19-59 years	GTCS (21), PNES (20), CPS (5).
Johansson et al. (2019)[36]	2	Wrist 3D-accelerometer	Prospective/Offline	18-77 years (median 35 years	Tonic-clonic seizures
Szabo et al. (2015)[37]	2	Surface EMG	Prospective/Offline	14-64 years (mean 40 years)	Generalized tonic-clonic seizures.
Halford et al. (2017)[38]	2	Surface EMG	Prospective/Offline	3-72 years	Generalized tonic-clonic seizures. "Intent to monitor cohort" (IMC), and "properly placed cohort" (PPC).
Beniczky et al (2018)[39]	3	Surface EMG	Prospective/Real-time	10-62 years (mean 34)	Generalized tonic-clonic seizures.
Boon et al. (2015)[40]	2	Cardiac-based seizure detection algorithm (Aspire)	Prospective/Offline post-hoc analysis of various thresholds	Not reported	Focal seizures (unspecified), Simple partial seizure, Complex partial seizure, Secondarily generalized, Other seizures.

Number of patients with seizures.	Number of seizures	Sensitivity	False alarm rate	Device deficiency time	Detection latency
15	22	20 of 22 (90.9%)	0.11/24 h (0 at night).	Not reported	17 s of onset of motor component (range, 12-35 s).
20	39	35 out of 39 (89.7%)	0.2/24 h (0 at night).	Time not reported. However, device deficiency was reported 15 times in total.	Mean 33 s from onset of GTCS and 55 s from onset of focal seizure (95% [CI] 38-73 s).
41	191	GTCS: 16/51 (31%). Myoclonic, tonic, myoclonic-tonic seizures: 3/32 (6%). Partial-onset seizures with motor component: 11/45 (24%). Partial onset with minimal motor component: 1/63 (2%). Total 16%.	Not reported	Not specified. However, two seizures were excluded because it is unknown if the SmartWatch was activated, two because the watch was disconnected, and two because the video was not available.	Not reported
12 (all seizure types) 10 (GTCS)	13 GTCS and 49 non-GTCS	12 of 13 GTCS (92.3%). No focal seizures were detected.	Not specified, but there was a total of 81 FPs.	Not specified, but three patients were excluded.	Not reported
12	21	20 of 21 (95.23%)	Mean: 0.72/24 h.	Not reported	Not reported
71	Seizure number not applicable (in-field study)	Median: 90%.	Median: 0.1/24 h. (mean =1.4/24 h.) – increased in a subgroup with >5 seizures/day.	7 cases (10%) stopped using device.	Not applicable (in-field study)
20	46	40 of 46 (20/21 GTC)	1.16/24 h, (GTCS only - 0,64/24 h).	Not reported	Not reported
11	37	I[a]: 10 of 10 II[a]: 9/10 III[a]: 9/10	I[a]: 1.2 FP/24 h. II[a]: 0.24 FP/24 h. III[a]: 0.48 FP/24 h.	22% (total of 1952 hours) in 29 patients (average 65 h/pt) missing data.	Not reported
11	21	20 out of 21	0.017/24 h (0 during sleep).	Not reported	Mean 15.2 s of onset of GTCS (range 4-56 s).
61	46 GTCS in the IMC, 29 GTCS in the (PPC).	In the IMC, 35 of 46 GTCS. In the PPC 29 of 29 GTCS.	In the IMC, mean FAR: 2.5/24 h. In the PPC, mean FAR: 1.4/24 h.	Not reported	Average: In the IMC: 7.45 s In the PPC: 7.75 s.
20	32	30 out of 32 (93,8%)	0.67/24 h.	<5%	9 s
16	Focal seizures: (unspecified) 8, Simple partial 26, CPS 31, sGTCS 17, Other seizures 5	I[a]: 11/11 II[a]: 16/27 (59.3%). III[a]: 7/15 (46.7%). IV[a]: 8/23 (34.8%) V[a]: 3/11 (27.3%). VI[a]: 3/16 (18.8%).	False positive rate per hour: I[a]: 7.15 (5.31, 9.94). II[a]: 2.72 (1.70, 3.91). III[a]: 0.49 (0.20, 0.96).	Not reported	Median: I[a]: 6.0 s II[a]: 27.5 s III[a]: 35.0 s.

(Continues)

TABLE 2 (Continued)

Study	Phase	Modality	Study design	Patient age range	Types of seizures
Fisher et al. (2016)[41]	2	Heart rate (ECG)	Prospective/Offline	21-69 years	Simple partial seizure, Complex partial seizure, Secondary generalized seizures.
Vandecasteele et al (2017)[42]	2	Heart rate (ECG and photoplethysmography (PPG))	Prospective/Offline	19-67 years	Complex partial seizures.
Jeppesen et al. (2019)[43]	2	Heart rate (ECG)	Prospective/Offline	4-79 years (median 34 years)	Focal seizures and Convulsive seizures (FBTCS & GTCS)
Karayiannis et al. (2006)[44-46]	2	Video	Retrospective/Offline	Not reported	Myoclonic seizures (80 segments), focal clonic seizures (80 segments).
Geertsema et al. (2018)[47]	2	Video-based algorithm in a residential care setting.	Retrospective/Offline	Not reported	Convulsive seizures (generalized clonic and generalized tonic-clonic seizures) and tonic >30 s, hyperkinetic, major motor seizures.
Arends et al. (2016)[48]	2	Sound detection	Prospective/Offline	18-42 years (mean 34 years)	GTCS, clonic seizures, tonic generalized seizures.
Narechania et al. (2013)[49]	2	Under-mattress device (ElectroMechanical Film Emfit®)	Prospective/Real-time	18-81 years (mean 38 years)	Generalized tonic-clonic seizures.
Fulton et al. (2013)[50]	2	Two under-mattress devices. (ST−2 model and Medpage Model MP5 devices)	Prospective/Real-time	1-22 y	9 GTCS; 8 secondary GTCS; 10 complex partial; 2 simple partial-motor; and 40 generalized myoclonic, tonic, or myoclonic-tonic.
Baldassano et al. (2017)[27]	2	Intracranial EEG	Retrospective/Offline	Not reported	Focal seizures
Gu et al. (2018)[51]	2	Behind-the-Ear-EEG	Prospective/Offline	19-64 years (mean 36 years)	Focal onset impaired awareness seizures.
Baldassano et al. (2019)[26]	2	Closed-loop implantable neural stimulators	Retrospective/Offline	Not reported	Electrographic focal-onset seizures

Number of patients with seizures.	Number of seizures	Sensitivity	False alarm rate	Device deficiency time	Detection latency
16	89	28 of 38 seizures with impaired awareness and GTCS (74%). 7 of 37 (19%) SPS.	216/24 h (with setting: 20% increase in HR).	Not reported	8 s (with 20% HR increase).
11	47	The wearable ECG 70%. The PPG 32%.	ECG: 50.64/24 h, PPG: 43,2/24 h.	Not reported	Not reported
43	126	Best algorithm: 93.1% of all seizures from responders. (90.5% of focal seizures, 100% of convulsive seizures).	1.0/24 h. (0.11 during sleep at night)	Not reported. However, data from 1 of 100 patients was excluded due to bad connection.	30 s. (median latency from first clinical or EEG sign of seizure).
54	160	>95% scheme 1. <95% scheme 2.	Not applied but specificity was: >90% scheme 1 and <95% scheme 2.	Not reported	Not reported
Training set: 50 patients, Test set: 12 patients.	Training set: 72 convulsive seizures, Test set: 50 convulsive seizures.	100% for convulsive seizures. 3/5 (60%) "hyperkinetic" seizures. 6/9 (67%) other "major" seizures.	Median false detection rate: 0.78 per night (8 h).	Not reported	CS: ≤10 s in 78% of detections from the start of the oscillatory period. Hyperkinetic and other major: 7-35 s.
10	112	81% (range 33%–100%).	Mean FAR 1.29 per night, due to minor seizure.	Not reported	Not reported
13	18	16 out of 18	0.13/24 h (0 at night).	Not reported	9 s of onset of bilateral clonic motor movement (range: −37 to +39 s).
15	69	MP5 bed monitor: 4.3% (1/23) (a generalized detected). The ST−2: 2.2% (1/46) (a complex partial detected).	Not reported	Not reported, however four patients found the MP5 device too uncomfortable and asked that it be removed.	Not reported
8 patients and 4 dogs in competition test set, 18 patient validation data set	95 in competition test set, 393 in validation set.	Performance was measured with AUC. Best algorithm had 0.975 test set, and 0.963 in validation dataset	Threshold of 1 FP/24 h of interictal data was preset to test the seizure detection sensitivities computed at a specificity.	Not reported	Not reported
12	47	Median 94.5%, Mean 82.17%	12.48/24 h	Not reported	Not reported
11	982	99%	0.72/24 h	Not reported	Not reported

(Continues)

TABLE 2 (Continued)

Study	Phase	Modality	Study design	Patient age range	Types of seizures
Jeppesen et al. (2015)[52]	2	Near Infrared Spectroscopy (NIRS)	Prospective/Offline	20-58 years (median 39 years)	Focal seizures. 20 temporal-, 11 frontal-, 2 parietal- lobe, one unspecific.
Onorati et al. (2017)[53]	2	Wristband electrodermal activity (EDA) and accelerometer	Prospective/Offline	4-60 years	Focal tonic-clonic seizures and focal to bilateral tonic-clonic seizures.
van Andel et al. (2017)[54]	2	Heart rate (ECG) and accelerometer	Prospective/Offline	2-65 years (median 15 years)	Generalized tonic-clonic seizures, Generalized tonic seizures, Hypermotor seizures, Clusters of short myoclonic/tonic seizures.
Cogan et al. (2017)[55]	2	Heart rate (ECG), arterial oxygenation, electrodermal activity	Retrospective/Offline	21-64 y	Secondary GTCS, CPS, Bilateral tonic, primary GTCS.
Arends et al. (2018)[24]	3 & 4	Heart rate (photoplethysmography) and 3D-accelerometer	Prospective/Real-time – during the night	15-67 years (mean 29 years)	Tonic-clonic, generalized tonic >30 seconds, hyperkinetic, clusters (>30 min) of short myoclonic/tonic seizures.

Abbreviations: CI, confidence interval; CPS, complex partial seizures; ECG, electrocardiography; EMG, electromyography; FAR, false alarm rate; FBTCS, focal to bilateral tonic-clonic seizures; FP, false positive; GTCS, generalized tonic-clonic seizures; IMC, intent to monitor cohort; PNES, psychogenic nonepileptic seizures; PPC, properly placed cohort; PPG, photoplethysmography; sGTC, secondary generalized tonic-clonic seizures; SPS, simple partial seizures.

aSensitivity/Detection latency/False positive depended on the threshold settings and/or detection method applied.

For other seizure-types only phase 2 studies were available. Best performance (sensitivity of 99%) was achieved by automated analysis of EEG recorded with intracranial electrodes[26,27] (Table 2). Of the noninvasive devices, sensitivity >90% has been achieved using heart rate and heart rate variability (Table 2).

5 | EVALUATING THE EVIDENCE AND FORMULATING THE RECOMMENDATIONS

We evaluated the quality of the evidence, using the GRADE approach, with specific consideration for the aspects related to diagnostic tests and strategies.[2,3] We assessed the factors that decreased the quality of evidence for diagnostic tests, specifically adapted to the topic of this CPG. We considered phase 3 validation studies to provide high level of evidence, phase 2 studies to provide moderate level of evidence, and phase 1 studies to provide low level of evidence. For each clinical question and each seizure type, we considered the studies with the highest available evidence (Table 3). In addition to the evidence, we evaluated the determinants of the strength of recommendations, adapted to the topic of the CPG (Table 4). We used a Delphi process to develop consensus-driven conclusions.[28]

The Working Group found high-quality evidence for detection of GTCS and FBTCS, and moderate evidence for seizures without a tonic-clonic component. Although there was broad consensus concerning the need for automated detection of both seizure categories, the Working Group considered that for the currently available devices it was uncertain whether the desirable effects (seizure detection) outweigh undesirable effects (eg, false alarms, burden of usage, and cost) for seizures other than GTCS and FBTCS. There is evidence from a single study (phase 4) suggesting that the use of automated seizure detection devices helped prevent injuries related to GTCS.[25] Although there is compelling evidence that SUDEP occurs mainly in unsupervised patients with GTCS, it was uncertain whether detection of such seizures could lead to sufficiently rapid and

Number of patients with seizures.	Number of seizures	Sensitivity	False alarm rate	Device deficiency time	Detection latency
15	34	12 parameters analyzed. Detection sensitivity was 6%–24%	Not reported	Not reported	Not reported
22	55	Best classifier: 94.55%	0.2 pr. day. FAR/ seizure: 0.91.	Not reported	Median =29.3 s (range =14.8-151 s).
23	86	Sensitivity 71% for all seizures and 87% for "clinically urgent seizures"	2.3-5.7 per night (8 h).	Due to failures in connection data from 52 of 95 patients could not be used. 8 pts data could only be partially used.	Average delay: 13 s.
10	26	I[a]: 11 of 11 from 7 patients. II[a]: 10 of 10 from 6 patients.	I[a]: Potential False positive 0.36/24 h II[a]: Potential False positive 0	Not reported	Not reported
28	809	TCS: 81%. Other major motor seizures: 77%. Median detection rate per patient: 96% for GTCS, 86% for all major motor seizures.	0.03 per night (95% CI 0.01-0.05).	Device deficiency time was present, but time-length not specified.	Not specified. Seizures were considered detected if within 3 min before and 5 min after onset.

effective intervention.[29] All terminology used for grading the evidence aligns with that which is inherent in GRADE methodology (Table S2).[2,3]

5.1 | Recommendations for automated seizure detection using wearable devices

The ILAE-IFCN Working Group recommends using clinically validated wearable devices for automated detection of GTCS and FBTCS when significant safety concerns exist, especially in unsupervised patients who do not share a bedroom but where alarms can result in rapid intervention, within 5 minutes (weak/conditional recommendation).

The ILAE-IFCN Working Group, at present, does not recommend clinical use of the currently available wearable devices for seizure types other than GTCS and FBTCS, as more research and development are needed for this application (weak/conditional recommendation).

There is need for further research and development in the following areas:

1. To increase the performance of wearable devices and detection algorithms (higher sensitivity and lower false detection rate), especially for seizures without generalized convulsions.
2. To decrease (even off-line) the false alarm rate, allowing objective documentation of seizure frequency.
3. To conduct properly designed clinical validation studies.
4. To demonstrate whether automated seizure detection leads to meaningful clinical outcomes, such as decreased morbidity and mortality associated with seizures, objective seizure quantification, and improved quality of life.
5. In-field (phase 4) studies are needed to provide a more accurate estimation of the false alarm rate. Similarly, costs, patients' preferences and perspectives should be considered in the evaluation of the impact of this technology.

This CPG has been endorsed by both the ILAE and IFCN, after being reviewed by the International Bureau for Epilepsy and after public comments. Because this is a rapidly developing field, we suggest updating this guideline at regular intervals (eg, every 2 years) or when high-level evidence is published that would influence the recommendations.

TABLE 3 Evaluating the evidence

	Quality assessment							№ of	Effect			
Seizures	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Detection modalities	Patients with seizures	Seizures	Sensitivity	FDR	Quality	Importance
GTCS & FBTCS	3	Phase 3	Not serious	Not serious	Not serious	Not serious	Accelerometry, sEMG, multimodal	68	880	90%–96%	0.2–0.7	HIGH	CRITICAL
Without TC component	8	Phase 2	Serious	Not serious	Not serious	Serious	EEG, PPG, ECG	152	1906	32%–90%	0.7–65	MODERATE	IMPORTANT

Abbreviations: ECG, electrocardiography; FBTCS, focal to bilateral tonic-clonic seizures; FDR, false detection rate (number of false detections/24 h); GTCS, generalized tonic-clonic seizures; PPG, photoplethysmography; sEMG, surface electromyography; TC, tonic-clonic.

6 | DISCUSSION

These recommendations for using wearable automated seizure-detection devices are based on a systematic review of the evidence in published literature, using a rigorous methodology (GRADE) for making recommendations, and are meant to lay out guiding principles for patient management. However, the decision to recommend or not a wearable device to an individual patient is up to the physician treating the patient, and this decision should be tailored to each individual. The wording of the recommendations is according to GRADE: The assessed intervention is either recommended or not recommended. For applications lacking sufficient evidence at the time of the guideline development, the wording "does not recommend" applies. However, this should not hamper further research and development in the field, but rather stimulate it. To facilitate this, we have highlighted the major areas where further work is needed.

When reviewing the published evidence, we included only phase 2-4 studies, due to the high risk of bias in phase 0-1 studies. Therefore, we did not include into Table 2 the pilot studies of the modalities that later led to more robust validation studies.[56–60] Including several hundreds of phase 0-1 studies on devices and algorithms that were promising, but not properly validated yet, was beyond the scope of this working group. Two phase 2 studies were published after the date last searched (October 16, 2019), and therefore not included.[61,62] However, the message of these studies would not have changed the recommendations. In a phase 3 study, 14 patients were previously enrolled in a phase 1 study.[24] However, in the phase 3 study, new data sets (new recordings and seizures) were recorded prospectively in these patients too. Although the study qualifies as phase 3, this was an important limitation of that study, because seizures tend to be very stereotyped in a given patient.

We found a high-level of evidence that the validated wearable devices accurately detected GTCS and FBTCS. However, there were only two "in-field studies" (phase 4)[24,25] addressing the applicability, feasibility in the home environment, and clinical benefit of the devices. Although evidence is scarce, data from one phase 4 study suggest that a device decreased the number of injuries associated with tonic-clonic seizures.[25] In addition, based on the existing evidence regarding the association between nocturnal supervision and the risk of SUDEP, the practice guidelines of the American Academy of Neurology provide the following recommendation: "Recommendation 4. For persons with frequent GTCS and nocturnal seizures, clinicians may advise selected patients and families, if permitted by their individualized epilepsy and psychosocial circumstances, to use nocturnal supervision or other nocturnal precautions, such as the use of a remote listening device, to reduce SUDEP risk (Level C)."[63] We believe that GTCS-detecting devices triggering an alarm can be assimilated to remote listening devices, and that the above level C recommendation would apply to both types of devices. In our recommendation, by unsupervised

TABLE 4 Determinants of the strength of recommendations

Factor	Considerations	GTCS & FBTCS	Seizures without TC component
Balance between desirable and undesirable effects	Do desirable effects (seizure detection) outweigh undesirable effects (ie, false alarms, burden of usage)?	Yes	Uncertain
Values and preferences	Do patients, caregivers, and healthcare personnel need wearable seizure detection devices?[a]	Yes	Yes
Wise use of resources	Does currently available automated seizure detection provide input for meaningful outcome (prevention of injuries, prevention of SUDEP, objective measurement of seizure burden) or increase in the quality of life?	Uncertain	No

Abbreviations: FBTCS, focal to bilateral tonic-clonic seizures; GTCS, generalized tonic-clonic seizures; TC, tonic-clonic.

[a]Numerous studies demonstrated that patients, caregivers and healthcare personnel need wearable seizure detection devices.[13–17,67–69]

patients, we meant patients sleeping alone and without other form of supervision (eg, CCTV). This was based on the risk-assessment: Patients not sharing a bedroom and having at least one GTCS or FBTCS per year had a 67-fold increased risk of SUDEP.[11] Weighing the published evidence (ie, high-level evidence that devices are "effective" in detecting tonic-clonic seizures, and the scarce/indirect evidence about their clinical benefit) resulted in a weak, conditional recommendation.

We found evidence that in some patients, seizures other than GTCS and FBTCS can be reliably detected. However, this derived from phase 2 studies with lack of evidence for the feasibility of pre-selecting the suitable patients and for the associated clinical benefit. Therefore, the working group considered that these were not sufficient for issuing a positive recommendation. Further research and development are needed in the field to validate use of automated seizure-detection devices for seizure types other than GTCS and FBTCS.

We identified only two in-field (phase 4) studies using devices validated in phase 3 studies.[24,25] There is a need for more in-field studies for numerous reasons: (a) a more realistic estimation of the false alarm rate in the home environment of the patients; (b) assessment of the feasibility of ultra-long-term use of these devices, including patient groups with additional challenges (comorbidities, disabilities); (c) estimation of the proportion of time with device deficiency; (d) investigation of the ultimate clinical benefit of wearing the devices; (e) adherence to daily use. Wearables will be of benefit only to the degree that patients and families accept their long-term and everyday use as a means of autonomy without stigmatization. Assessment of the device retention rate in phase 4 studies will be important.

The goals of the working group included reviewing the published evidence for using wearable devices to improve the objective documentation of seizure frequency.[64] However, the current rate of false alarms might overestimate the true seizure frequency. Changes over time in FAR could also lead to misleading within-patient trends of the detected event rate. For example, the FAR depends much on the activity level of the patients. The increased number of alarms in the more active period (due to the false alarms) might erroneously suggest an increase in seizure frequency. Although patients or caregivers can confirm or cancel alarms, the validity of these decisions is questionable. Furthermore, we did not identify high-level evidence for the accuracy or for the clinical benefit of seizure quantification using the currently available wearable devices. Therefore, based on the methodology we used, we were not able to issue a recommendation for this application—at present. However, we fully agree on the importance of objective seizure quantification and we listed this under "need for further research and development." Several approaches seem to be promising for solving the issue of false alarms for seizure quantification. Off-line visual analysis by experts, of the surface EMG signals automatically detected by an algorithm resulted in accurate validation of the events.[65] Off-line analysis of the biosignals, using cloud-computing and artificial intelligence could provide more accurate seizure detection.[66]

ACKNOWLEDGMENTS

We express our gratitude to those who sent us comments on the draft version of the CPG.

CONFLICTS OF INTEREST

Author SB served as a scientific consultant for Brain Sentinel and Epihunter. WOT was principal investigator for the clinical trial using Brain Sentinel device. The remaining authors do not have any conflict of interest to disclose, related to this work.

ETHICAL PUBLICATION STATEMENT

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Beniczky S, Wiebe S, Jeppesen J, et al. Automated seizure detection using wearable devices: A clinical practice guideline of the International League Against Epilepsy and the International Federation of Clinical Neurophysiology. *Epilepsia*. 2021;62:632–646. https://doi.org/10.1111/epi.16818